Utah Department of Health

CLINICAL LABORATORY BULLETIN November 2006

Web page: http://health.utah.gov/lab/labimp

❖ INTRODUCING:

Steve M Dickson	Virology
Omar Rauf	Environmental Chem
MeGarin Stock	Environmental Chem

NOTEWORTHY

✓ **Understanding the blood clotting process:** Rustem F Ismagilov, chemistry professor at the University of Chicago, and his graduate students created a microfluidics system to parallel blood clot initiation. They divided this complex process into three modules to simulate the kinetics of the clotting process. Autocatalytic production of clotting activators, depletion of the activator by diffusion, and clot formations at high activator concentrations.

Ismagilov feels the important measure of clotting is not the concentration of each individual clotting factors. "You actually have to know the localization of tissue factor." The team will apply their research results to a model organism and then to humans.

For more about the research read the article - *ProcNatl.Acad.Sci.* USA 2006, 103, 15747.

✓ **Spinning blood tubes:** The BD Vacutainer Evacuated Blood Collection System package insert has a section for centrifugation on page 3. There is a caution against spinning glass tubes above 2200 RCF in a horizontal head (swinging bucket) or above 1300 RCF in a fixed angle head centrifuge. They give RCF and spin times for 6 different types of tubes (glass and plastic) and a formula to calculate revolutions per minute (rpm) for your centrifuge. Check your collection tube insert.

✓ **Blood collection – Ø fingerstick:** Lisa O. Ballance, BSMT(ASCP) wrote an editorial entitled "Phlebotomy Q&A: The Five Pitfalls of Fingerstick Collections" for the September issue of Lab-Oratory (North Carolina's Public Health newsletter). She describes five cases when fingerstick blood collection is contraindicated:

1. Patient is less than 12 months old (use heel-stick on prewarmed surface).
2. Using a finger on the same side of the body as a prior mastectomy.
3. Finger was used recently or is injured / swollen.
4. Test requires venous specimen.
5. Patient is dehydrated or has poor circulation.

CONTENTS

✓ **Check control compatibility with your test method:** Before you use a set of "cheaper" controls from a different manufacturer than your instrument or method, check the package insert of both. For example, Bio-Rad states on the Lyphochek information sheet their linearity set has assayed values for several Bio-Rad instruments: the Roche Cobas Integra, Tosoh A_{1c} 2.2 Plus, and the Dade Behring Dimension RxL. Before you use this linearity set, check your instrument's package insert to make certain the manufacturer does not specify a particular linearity set(s) excluding Bio-Rad. The same process is necessary for quality control materials. The control manufacturer must give you acceptable ranges for your instrument / reagent combination or particular method using their product. Your current instrument or method must not preclude using controls from an outside source.

✓ **Fungi in your contact lens solution:** A filamentous fungus, genus *Fusarium*, is identified in worldwide literature as the cause of keratitis (infection in the eye cornea). Recent reports show the organism was found in contaminated, commercial contact lens solutions.

Fusarium species are known to infect plants and are found as saprophytes in soil and plants. Infection in humans is rare (unless they use contaminated contact lens solution). *Fusarium* is usually found as an opportunistic pathogen in burn victims and immunocompromised patients. They are very resistant to antibiotic treatment. Topical natamycin is used to treat keratitis.

For more information on the contaminated lens solutions, check:
MMWR. April 10, 2006. 55(Dispatch): 102.
Khor, Wei-Boon, et al. 2006. *JAMA*, 296(24):2867-2873.

MMWR. May 26, 2006. 55(20):563-564.

✓ **Validating a new lot of reagent:** In the June 2006 issue of Lab Medicine is an article with an interesting approach to validating whether a new lot of reagent is giving you acceptable patient results. The authors, from the University of Alberta Hospitals and Capital Health Authority of Edmonton, use one of three different methods. They argue one validation method does not fit all – especially if you have a dry reagent system such as Vitros. For each instrument, decide which of the following categories best fit your situation each time you change reagent lots.

A. Tests for which only quality control results are evaluated. Examples include: unstable analytes – ACTH, insulin, etc.; highly unstable reagents – bile acids, free fatty acids; little or no specimen for repeats – tissue iron or copper; test is too laborious – fecal fats.

B. Quality control validation for methods with usually clinically unimportant lot-to-lot variation. Examples include: electrolytes, calcium, total protein, etc, performed on certain instruments.

C. Patient-based reagent lot validation for methods with significant lot-to-lot variation. Examples include: troponin, hCG, folate on certain instruments, and enzyme or turbidimetric test on the Beckman LX-20.

For the complete article, including detailed validation methods for the three cases above, go to www.labmedicine.com.

✓ **Psoriasis Gene:** Researchers at the University of Michigan feel they discovered the gene responsible for psoriasis. After extensive research on 5 persons enrolled in the study, the team felt allele HLA-Cw6 is responsible for people developing this unsightly disease. The HLA-C is one of several genes in the histocompatibility complex that regulate how the immune system fights infection.

Falsely elevated platelet count – case study: In the *J Clin Pathol*. 2004;57:1096-1097 is a report by Kakkar N. "Spurious rise in the automated platelet count because of bacteria." A patient was admitted to a coronary care unit with difficulty breathing. She had a mitral valve replacement 11 years prior to admission. Her blood count was fairly normal except for a platelet count of $1152x10^9$. A peripheral blood smear was examined. It showed approximately $130x10^9$ platelets and rod-shaped bacteria! The clinicians, fearing bacteremia of the valve did an intensive patient work up. Finally someone discovered the blood sample initially tested had been in the emergency department for 8 hours before it was delivered to the lab. A repeat sample had a platelet count of $158x10^9$.

✓ **Mycobacterium lurking at your nail salon:** Pampering yourself could have unwanted consequences. An outbreak in 2000 of *M. fortuitum* in a California nail salon resulted in 100 infected customers. Likewise, the same species was found in contaminated footbaths in 2002 resulting in 115 persons experiencing lower extremity boils. In 2003 two persons had lower extremity furunculosis caused by *M. mageritense*. Both persons had received footbaths before pedicures from the same salon. Both these organisms thrive in water sources. So what can you do?

Don't give up pedicures, just check the salon. Find out how they disinfect their baths. Do they wait long enough for the disinfectant to work before adding new water? Do they clean out all debris from the previous customer before starting on you? One infection investigation found the women shaved just before the pedicure. Tiny cuts or scrapes would allow these fast growing mycobacteria to cause infection. Drains and screens harbor bacterial biofilms – lovely, protective bacteria communities. Are they cleaned regularly?

✓ **Cystic fibrosis screening:** The standard sweat chloride test has been around since I was in elementary school. The quantitative pilocarpine iontophoresis (QPI) method is the "gold" standard. In this new century is there something as accurate but less time consuming and less error prone? J. Barben et al. from Children's Hospital in St. Gallen Switzerland believe so. They published an article in *J pediatr*. 2005;146:183-188. Their review of several studies show osmometry and conductivity sweat evaluations are as effective as QPI for diagnosing cystic fibrosis. These methods are quicker and don't require as much technical expertise to perform.

The authors conclude conductivity and osmometry can be used for cystic fibrosis screening and diagnosis.

FROM THE PATIENT'S CHART

"Patient was seen in consultation by Dr. Blank, who felt we should sit on the abdomen and I agree."

☆ Feature ☆

Clinical Laboratory Improvement Amendments (CLIA)

Verification of Performance Specifications

Brochure #2

What is it and how do I do it?

The CLIA regulations now include a requirement for verifying the performance

specifications of unmodified, moderate complexity tests cleared or approved by the FDA.

Information to assist your laboratory in meeting this CLIA requirement!

NOTE: On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final laboratory regulations (CLIA) that became effective April 24, 2003. A summary of the updated requirements are included in this brochure. However, this brochure is not a legal document. The official CLIA program provisions are contained in the relevant law, regulations and rulings. For more complete information, you may access the regulations on the Internet at http://www.phppo.cdc.gov/CLIA/regs/toc.asp

BACKGROUND

The CLIA Quality System Regulations became effective on April 24, 2003. Now the laboratory is required to check (verify) the manufacturer's performance specifications provided in the package insert--for accuracy, precision, reportable range, and reference ranges--for each new unmodified, moderate complexity test that the laboratory performs before reporting patient test results. The verification process helps to assure that the test, when used in your laboratory by your testing personnel for your patient population, is performing as the manufacturer intended.

This requirement applies when the laboratory **REPLACES** a test system or instrument (with the same model or a different model); **ADDS** a new test; or **CHANGES** the manufacturer of a test kit.

The requirement does not apply to tests performed by the laboratory before April 24, 2003.

TIP! While the laboratory's technical consultant or director should be involved in the planning and evaluation of the performance specification checks, the test system manufacturer may also assist by providing a verification protocol and appropriate samples for the evaluation.

ACCURACY

Are your test results correct?

The laboratory needs to compare the accuracy of the test results it obtains when using a test system with the manufacturer's accuracy claims. This can be done by testing commercially available calibrators/calibration and quality control materials with known values, proficiency testing materials that have established values, and previously tested patient specimens with established values. If test results for these samples fall within the manufacturer's stated acceptable limits, accuracy is verified.

PRECISION

Can you obtain the same test result time after time?

The laboratory is responsible for verifying that it can repeatedly test the same samples on the same day, and on different days and get the same or comparable results (reproducible), regardless of which member of the laboratory's testing personnel performs the test (operator variance). Several of the laboratory's testing personnel should participate in this evaluation to help determine overall laboratory variance. Exception: For fully automated test systems that are not operator dependent, operator variance should not affect the test's precision and may not need to be evaluated by more than one person.

REPORTABLE RANGE

How high and how low can test result values be and still be accurate?

To verify the manufacturer's established reportable range for the test, choose samples with known values at the highest and lowest levels the manufacturer claims accurate results can be produced by the test system. The laboratory may only report patient test results that fall within the verified levels. The laboratory director and/or the technical consultant will need to decide how the laboratory will report results that are greater

than the highest verified level or less than the lowest verified level.

REFERENCE RANGES/INTERVALS (NORMAL VALUES)

Do the reference ranges provided by the test system's manufacturer fit your patient population?

You may begin patient testing using the manufacturer's suggested reference range(s) or you may use other published reference ranges from a textbook or a journal publication. Reference ranges can vary based on the type of patient (e.g., pediatric, male, female). Over time, you may need to adjust your reference range(s) to better fit the patient population(s)you routinely test. When you test known normal patients, the results should be within your reference range and with abnormal patients, you should expect results outside the reference range.

How many samples do I need to test?

While testing 20 samples is considered the "rule of thumb" for statistical purposes, this is not a magic number. Depending on the test system and the laboratory's testing volume, the actual number of specimens needed for each part of the verification study may vary.

Once the laboratory director has reviewed and approved the results of the verification studies, the laboratory may begin using the test system for routine testing and reporting patient test results. Conversely, if the study results indicate that the test is not accurate or results cannot be consistently reproduced, the laboratory's technical consultant and the test system manufacturer should be consulted regarding steps to resolve the problem.

TIPS! With planning, verifying a test system's accuracy; precision, including operator variance; and reportable range may be performed using the same samples. For example, you may test samples with known values at the upper and lower end of the manufacturer's reportable range along with samples that are in the normal range for your patient population, in different runs, on different days, using several of the personnel who will normally perform the testing. The activities of the personnel verifying the test system will also facilitate meeting CLIA's personnel competency requirements for these employees. In addition, the laboratory director may use the verification process to meet the CLIA requirements for establishing the test system's quality control protocol, an essential component of the laboratory's overall quality system.

Where can I find additional information about the CLIA requirements pertaining to the verification of performance specifications?

You may refer to the State Operations Manual, Appendix C-Interpretive Guidelines, §493.1253, available on the CMS website at: www.cms.hhs.gov/clia.

How are the final regulations being implemented?

CMS is allowing each laboratory that it inspects to have one educational survey following the April 24, 2003, effective date of the regulations. This will give laboratories time (2 years) and the opportunity to receive the technical assistance that may be needed to meet the updated requirements.

Where can I find additional information and guidance?

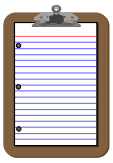
Assistance for meeting the requirements is provided in Appendix C of the State Operations Manual (CMS Publication 7), which is posted on CMS's CLIA Website. Information about CLIA and links to other laboratory-related resources can be found on the following Websites:

CDC: www.phppo.cdc.gov/clia/default.asp

CMS: www.cms.hhs.gov/clia/default.asp
FDA: www.fda.gov/cdrh/CLIA/index.html (for a listing of waived, moderate complexity and high complexity tests)

February 2004

[A printable copy of this brochure is available on the CLIA website: www.cms.hhs.gov/clia.]



CLIA BITS

ADDITIONAL WAIVED TESTS:

° OcculTech Fecal Occult Blood Rapid Test

°Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc) – whole blood

°ESA Biosciences LeadCare II Blood Lead Testing System – whole blood

°Arkray SPOTCHEM EZ Chemistry Analyzer – whole blood

°Little Nell Labs ThyroChek TSH (TSH – whole blood)

°Biosite Triage Meterpro (BNP-whole blood)

°Clarity *H. pylori* Rapid Test Device (serum/ plasma/whole blood)

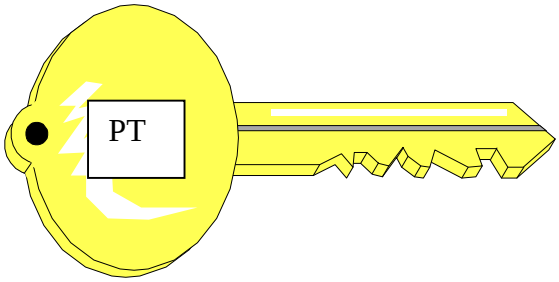
°HemoCue Hb 301 System

°Genzyme Diagnostics OSOM BVBLUE Test

°Biosite Triage Meterpro

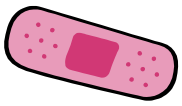
Equals

"Basic unit of laryngitis: 1 hoarsepower"



Cytology Proficiency Testing Update

There is still some misunderstanding about enrollment. As stated in the previous bulletin, every person screening or reading PAP smears must be tested each year. For persons who work at more than one site, they need only be tested once (not at each site). However, **each CLIA certified or accredited lab must be enrolled in proficiency testing** so the personnel's scores can be recorded in each lab where they are employed. The PT provider can tell you how to accomplish the documentation for persons working at multiple sites.



SAFETY

Microscope Ergonomics

Colleen Miller, BS MT(ASCP) gave some helpful tip in the December 2006 issue of Lab-

Oratory. If you spend a lot of time at the microscope, consider:
Eyes: Angle eyepieces no more than 30° above the desktop horizontal plane. Line them with or slightly over the bench edge.

Neck: Bend the neck and head no more than 10-15°.

Back: Sit erect and support the lumbar section.

Arms/wrists: Keep upper arms perpendicular to the floor and elbows close to the body. Support the wrists on a padded work surface keeping them straight.

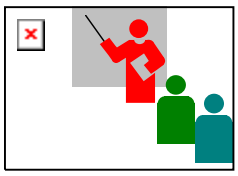
Legs: Leave "stretch room". Rest feet firmly on the floor or a footrest. The chair should apply even pressure to the back of the thighs.

(This sounds like the same stuff for computer work!) For an ergonomic tutorial check out www.microscopyu.com/tutorials/java/ergonomics/posture/index.html.

Ponderables:

How important does a person have to be before they are considered assassinated instead of just murdered?

CONTINUING EDUCATION



ASCT Cyto Course

The American Society of Cytotechnologists (ASCT) launched a Web course hosted by blackboard.com entitled "Introduction to the Cytopreparation Laboratory." The course is very basic and consists of an introduction and 7 chapters:

*Specimen receipt
*Specimen preparation
*Staining theory and purpose
*Equipment orientation/maintenance
*Troubleshooting common problems
*Quality assurance
*Safety

For more information contact ASCT at 800.948.3947 or email info@asct.com.

"Duct tape is like the Force. It has a light side, a dark side, and it holds the universe together."
Carl Zwanzig